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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/724,910	11/28/2000	Hugh J. Pa...	7414.0025	8658

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EXAMINER	
MAHATAN, CHANNING	

ART UNIT	PAPER NUMBER
1631	9

DATE MAILED: 05/15/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/724,910	Applicant(s) PASIKA ET AL.	
	Examiner Channing S. Mahatan	Art Unit 1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *1 March 2002, Paper No. 7* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-33* is/are pending in the application.

4a) Of the above claim(s) *1,2,4,5,7-13,16-24,26,27 and 29-33* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *3,6,14,15,25 and 28* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-33* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☒ The proposed drawing correction filed on *01 March 2002* is: a)☒ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) *2 Sheets* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☒ Other: *Decision On The Petition Filed* .

DETAILED ACTION

ART UNIT DESIGNATION

The Group and/or Art Unit designated for this application has changed. Applicant(s) are hereby informed that future correspondence regarding this application should be directed to Group Art Unit 1631.

PETITION FOR COLOR PHOTOGRAPHS

The petition to accept color photographs in Paper No. 8, filed 1 March 2002, is granted.

APPLICANTS' ELECTION

Applicants' election of Group II (claims 3, 6, 14, 15, 25, and 28) drawn to methods for making correct allele calls in respect to a predefined complexity filed 1 March 2002, in Paper No. 7 is acknowledged. However, applicants' failed to specify whether the election is with or without traverse. Therefore, since none was made the election will be treated as an election without traverse.

CLAIMS UNDER EXAMINATION

Claims herein under examination are claims 3, 6, 14, 15, 25, and 28.

Claims Rejected Under 35 U.S.C. § 112 2nd Paragraph

The following is a quotation of the second paragraph of 35 U.S.C. § 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 3, 6, 14, 15, 25, and 28 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

VAGUE AND INDEFINITE

Claims 3, 14, 25 and all claims dependent therefrom are directed to a method, system, and medium to "making correct allele calls", however the actual claim steps etc. lacks the limitation which is directed to "making correct allele calls". It is noted that the "determining" of claim 3, line 3, for example, is utilized in line 4 for making an allele call, but confusingly without stating what defines the "correct allele call". Applicants' can resolve this issue by particularly pointing out whether a "correct allele call" is determined by a signal which is: 1) below a "predefined complexity" or 2) at said complexity or 3) above said complexity. All three-signal characteristics are presumably possible for the practice of claim 3, but without clarification of what signal characteristic results in a "correct allele call" it is confusing. Clarification is requested via clearer claim wording.

Claims 3 (line 3), 14 (line 5), 25 (line 4), and all claims dependent therefrom recites "complexity" which is vague and indefinite. The metes and bounds of the claims are unclear since the applicants fail to point out what would be encompassed by the term "complexity". Clarification is requested via clearer claim wording.

Claims 6 (lines 1-2), 15 (lines 1-2), and 28 (lines 1-2) recites the phrase "nucleic acid information is nucleic acid length" which is vague and indefinite. Claims 3, 14, and 25 (which claims 6, 15, and 28 depends, respectively) indicates receiving a signal "representing nucleic acid information". However, the specification indicates that signal complexity is first determined on the basis of whether three panels exist and then computes the energy for each panel etc (p 14, lines 15-18). Thus, signal analysis requires at least panel determination and energy computation, hence, the signal must contain more than nucleic acid length information.

Therefore, claims 6, 15, and 28 are vague and indefinite in that the signal is apparently characterized therein as being represented by only nucleic acid length information. Clarification is requested via clearer claim wording.

Claims Rejected Under 35 U.S.C. § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. § 102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the examination of this application as the application being examined was not (1) filed on or after November 29, 2000, or (2) voluntarily published under 35 U.S.C. § 122(b). Therefore, this application is examined under 35 U.S.C. § 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. § 102(e)).

Claims 3, 6, 14, 15, 25, and 28 are rejected under 35 U.S.C. § 102(b) as being anticipated by Perlin (U.S. Patent No. 5,580,728).

Perlin teaches a method and system for determining the alleles of STR genetic markers (Abstract). Perlin states that stutter pattern often precludes the determination of alleles by overlapping to produce a complex signal, therefore, by combining the complex signals with the determined response functions of the repeat marker allele sizes can be determined resulting in a reliable genotyping (Column 2, lines 4-21). Nucleic acid material from a genome is obtained,

amplified, assayed based on size and concentration, and said assayed amplified material is converted into electrical signals (Column 5, lines 49-59). Following amplification, the amplified nucleic acids are size separated by gel electrophoresis which allows for allelic sequence length to be determined (Column 11 and 1, lines 16-18 and 43-47). Gel images are electronically scanned and put into machine readable digital format, wherein the data signals obtained enable the eventual quantitation of the nucleic acids and concentrations present in the amplified material (Column 11, lines 27-39). The data signals are recorded as a linear fluorescence signal trace, which is automatically creates machine-readable data files via software (Column 12, lines 8-11). Utilizing a computer device with memory via a program in memory the values of the assay signals are examined (Column 12, lines 26-28). Signal peaks are identified and assigned a time and an area, such that the apex of the peak (difference between right and left values) exceeds a predetermined threshold/complexity (Column 12, lines 47-54). Perlin illustrates and describes allele calling via deconvulution in Figure 1B, wherein a first and second set of electrical signals corresponding to a response pattern of the location is used to produce a third set of clean electrical signals thereby computing a single peak per allele (remove of overlapping stutter peaks) corresponding to the size and multiplicities of the unamplified material on the genome at the location (Column 13-14, lines 58-67 and 1-41). Thus, Perlin clearly anticipates the instantly claimed invention.

Claims 3, 6, 14, 15, 25, and 28 are rejected under 35 U.S.C. § 102 (e) as being anticipated by Hiller et al. (U.S. Patent No. 6,274,317 B1).

Hiller et al. teaches a computer system for allele calling based on matching and assigns a quality factor (Abstract). Allele length is measured by separating amplified DNA segments by

length in lanes on an electrophoresis gel (Column 1, lines 50-52). The method is executed in a computer system, which identifies alleles from trace data (Column 2, lines 32-41). A computer program residing on a computer readable medium possesses the instructions for causing a computer to apply a typical shape of an allele for a marker to the trace to identify potential allele calls that match to the typical shape of the allele at the marker and assign a quality factor to the allele calls (Column 2, lines 42- 60). Amplified DNA material is run on an electrophoresis gel, so that when electric current is applied the segments of DNA travel through the gel at a rate inversely proportional to their length (Column 3, lines 41-44). A DNA sequencer is utilize where a laser scans the gel and produces a gel image in a machine-readable, digital format (Column 3, lines 47-48). Said digital format is a color-coded pixel image, which is stored on in a file server (Column 3, lines 58-60). Additional heuristics are/can be applied to filter the output from the auto allele caller module, for example adjacent peaks are filtered to within a predetermined number of base pair distance/threshold/complexity (Column 9, lines 24-64). Thus, Hiller et al. clearly anticipates the instantly claimed invention.

OBJECTION TO CLAIMS

Claims 6 and 28 are objected to because of dependency to claims 1, 4, 23, and 26, which is drawn to non-elected subjected matter.

OBJECTION TO DISCLOSURE

The disclosure is objected to because of the following informalities:

In the specification on page 5, the Brief Description of the Drawings is insufficient. A separate brief description of each drawing is required. It is noted that Figures 10-12 are not

separately briefly described. It is noted that such subpart drawings are present as Figures 3A-3D but not described on said page 5.

In the specification on page 14, Table 1, requires correction. The specification is required to be either double-spaced or at least 1 ½ spaced and not single spaced as in Table 1.

Appropriate Correction is Required.

No Claims Are Allowed.

INVENTORSHIP AMENDMENT

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(i).

EXAMINER INFORMATION

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 C.F.R. § 1.6(d)). The CM1 Fax Center number is either (703) 308-4242 or (703) 305-3014.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Channing S. Mahatan whose telephone number is (703) 308-2380. The examiner can normally be reached on M-F (8:30-5:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael P. Woodward, Ph.D., can be reached on (703) 308-4028.

Any inquiry of a general nature or relating to the status of this application should be directed to Patent Analyst, William Phillips, whose telephone number is (703) 305-3482 or to the Technical Center receptionist whose telephone number is (703) 308-0196.

Date: May 13, 2002
Examiner Initials: CSM

Ardin H. Marschel
ARDIN H. MARSCHEL
PRIMARY EXAMINER